Ethic Committee Approvals

Introduction

Responsibility for ensuring that all research is subject to appropriate ethics review and monitoring lies with the research organisation (RO) in this case: ICN School of Business. Initial responsibility lies with the individuals concerned, and the Research Management Committee, which serves as the School's Research Ethics Committee.

Each proposal should be subject to an appropriate ethics review process.

Researchers remain free and independent in the choice and manner of their research. The purpose of the Research Ethics Committee is to

- Help researchers reflect upon and discuss the ethical issues of their research;

- Offer guidance in the event of potentially sensitive research.

The School[1] will have clear, transparent and effective procedures for ethics review and governance leading to one of two outcomes:

Approval: researchers have fulfilled the requirements and received clearance; School assumes responsibility for any research ethics related problems if research is conducted as indicated in application and there is no obvious unethical behaviour (such as lying, cheating etc.).

No approval: all responsibility lies with the researchers; School may also decide against funding (seed funding scheme, conferences etc.) if ethical review is not undertaken or the outcome is negative

Initial responsibility for ethical approval lies with supervisors of academic projects (i.e. postgraduate projects, dissertations and theses) with specific regard as to whether ethical approval is mandatory or not. Where approval is sought, the Committee commits to first answer 14 days after submission of the complete application. Iterations may be necessary. It is the responsibility of the researcher to initiate the process in good time (see below):

[1] In accordance with the general and specific principles found in the French Charter for Research Integrity (January, 2015, 3pp; and the ICN Open Science Statement, version 1.0, January 9, 2023).

Does a study require ethical approval?

Decisions on the conduct of a study, including whether there is a need for ethical approval, is the responsibility of the person undertaking the research. A School such as ours requires that:

Researchers are required to consider the ethical risk of any procedure within a research project which involves human participation or personal data, consulting the relevant Faculty, Department, School policies and personnel, before any work is undertaken. Advice must be sought in case of doubt from the Research Ethics Officer (Associate Director Research).

Where more than minimal risk is identified, reasonable and proportionate independent ethical review must be carried out prior to research work commencing.

In practical terms studies that involve “more than minimal risk”, and therefore require ethical review, will include studies where the intention is to submit findings for publication in journals, oral presentations, books, web-pages, and other media, or as part of coursework (to include essays, dissertations, theses etc) which

- involve the collection or analysis of data that could be used to identify participants (including email addresses or other contact details)

- physical contact with participants

- any risk of discomfort or inconvenience to participants

- any risk of psychological distress to participants or their families

- participants recruited from vulnerable groups, in particular children and those whose capacity to consent to participation may be challengeable because they have a temporary, fluctuating, or permanent impairment in, or disturbance of the functioning of the mind or brain

- data collection that will be undertaken overseas.

If the study contains any of these elements, then ethical approval should be sought from the Research Ethics Committee.

Studies with data collection using on-line resources, even those that do not collect or store identifiable data, may require ethical review to ensure that participants are giving informed consent (e.g. are adequately warned of sensitive questions or images), that there are adequate safeguards against children taking part where appropriate, and that data storage meets current Data Protection regulations.

Some studies that do not require ethical approval include those involving information freely available in the public domain (e.g. published biographies, newspaper accounts), and the analysis of datasets, either open source or obtained from other researchers, where the data are properly anonymised and informed consent was obtained at the time of original data collection.

Regardless of whether or not ethical approval is necessary, in the vast majority of cases research with human participants requires appropriate consent.

What does a consent form look like:

Participant Information Sheets and Consent Forms are important aspects to the organisation and conduct of a study. The participant Information Sheet gives potential participants the necessary understanding for the motivation and procedures of the study and sources of information to answer any further questions to allow them to give informed consent. A Consent Form essentially reprises this information to ensure the key points are understood and then records this understanding, usually with a signature. Consent may also be recorded electronically, for example through web-forms by clicking a button. More than one Consent Form may be needed (for adults and children separately, for example). Consent Forms are usually in addition to Participant Information Sheets.

Participants aged 18 years and under generally require consent from parents or careers, and therefore Participant Information Sheets and Consent Forms are addressed to them in these circumstances. However, it might be appropriate to make a Participant Information Sheet and Assent Form for child participants using age-appropriate language.

Participant Information Sheets

The Participant Information Sheet (PIS) should be a clear and simple document, on headed paper with the School Crest (or equivalent for other institutions), that would be easily understood by those to whom it is aimed; for example, it should be age-appropriate. It should be a concise document; the length and design should encourage a potential participant to read it in full.

There is no set format, however investigators may like to consider including the following sections:

Title

Use a simplified title if the original title would be too technical

Invitation paragraph

A brief introduction; for example: *Before you decide to take part in this study it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. A member of the team (or the person undertaking the research) can be contacted if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.*

Purpose of the study

State the background and aim of the study. When will the study be completed?

Why have I been chosen?

Explain why the potential participant has been approached.

Do I have to take part?

Explain that taking part is entirely voluntary and that refusal or withdrawal will involve no penalty or loss, now or in the future.

What will happen to me if I take part?

Say where the assessments will take place, how many will there be, how long the assessments will be each time and what exactly will happen. What are the participant's responsibilities? Set down clearly what you expect of them.

What do I have to do?

Make clear if there are any lifestyle restrictions as a result of participating.

Make clear if video or audio taping will be used and if so, say when they will be destroyed. For example: *Tapes will be identified only by a code, and will not be used or made available for any purposes other than the research project. These tapes will be destroyed at the end of the study. Information retained will be anonymised and used only for the purposes of academic research.*

Are there possible disadvantages and/or risks in taking part?

Describe any reasonably foreseeable discomforts, disadvantages and risks.

What are the possible benefits of taking part?

Any benefits to the participants that can reasonably be expected should be stated. However, where there is no intended benefit to the participant from taking part in the project this should be stated clearly. It is important not to exaggerate the possible benefits to the particular participant during the course of the project. This could be seen as coercive.

Will my taking part in this project be kept confidential?

The participant's permission will be needed to allow restricted access to information collected about them in the course of the project. You should explain that all information collected about them will be kept strictly confidential and briefly described how this will be ensured. For example: *All data will be identified only by a code, with personal details kept in a locked file or secure computer with access only by the immediate research team.*

Bear in mind that investigators are responsible for ensuring that when collecting or using data, they are not contravening legal or regulatory requirements.

What will happen to the results of the research project?

You should be able to tell the participants what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which arm of the project they were in? You might add that they will not be identified in any report or publication. For example*: Results will be presented at conferences and written up as an academic project, dissertation or thesis. Results are normally presented in terms of groups of individuals. If any individual data are presented, the data will be totally anonymous, without any means of identifying the individuals involved.*

Depending on the nature of your proposed project, you may need to include a statement indicating that the data collected during the course of the project might be used for additional or subsequent research.

Who is organising and funding the research?

Name the organisation or company sponsoring or funding the research as needed.

Ethical review of the study

Example text: *The project has been reviewed by the ICN School of Business Research Ethics Committee.*

Contact for further information

You should give contact details of a named investigator (or the student concerned) for further information and what to do next should they want to take part.

Consent Forms

A Consent Form should be no longer than one side of A4. It should be formatted on headed paper with the School Crest (or equivalent for other institutions) and clearly stating the title of the study.

The Consent Form concisely covers the main points of the Participant Information Sheet phrased as statements with which potential participants can agree or disagree. You could add a space for initials or yes/no deletions.

Some example statements include:

- *I confirm that I have read and understand the Participant Information Sheet*
- *I have had the opportunity to ask questions and had them answered*
- *I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified (except as might be required by law)*
- *I agree that data gathered in this study may be stored anonymously and securely, and may be used for future research*
- *I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason.*
- *I agree to take part in this study*

Participant's signature

Make a space for the participant to sign, print their name and date. If parents or carers are consenting for a child, then a space to print the child's name is also needed. NB, if involving children, more detailed requirements are necessary.

Spaces for the investigator taking consent to sign, print their name and date can also be included.

Actual Consent Forms

These are almost as diverse as there are academic HEI's. One example can be found at:

Researcher-Checklist-of-Ethics-Applications-for-Research-with-Human-Beings.-102020.pdf (ukrio.org)

The main rationale is that the project/dissertation is planned for with ethical approval in mind, approval that should be sought for, discussed with one's supervisor, and – where necessary obtained.

A timeline would be:

1. Candidate is informed of ethical approval potential need
2. Ethical approval forms are discussed with supervisors of projects or dissertations
3. Supervisors in certain circumstances must ask students to submit their research proposal and form seeking ethical approval to the Research Ethics Committee (REC)
4. REC reviews forms, grants approval, or seeks further information/clarification before approval
5. Students are ambassadors of the School and should represent it well.